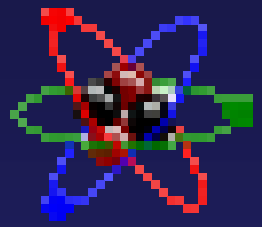
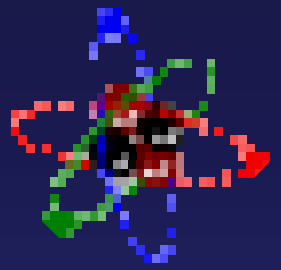

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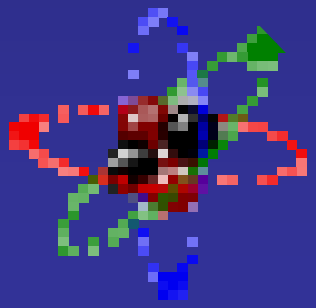
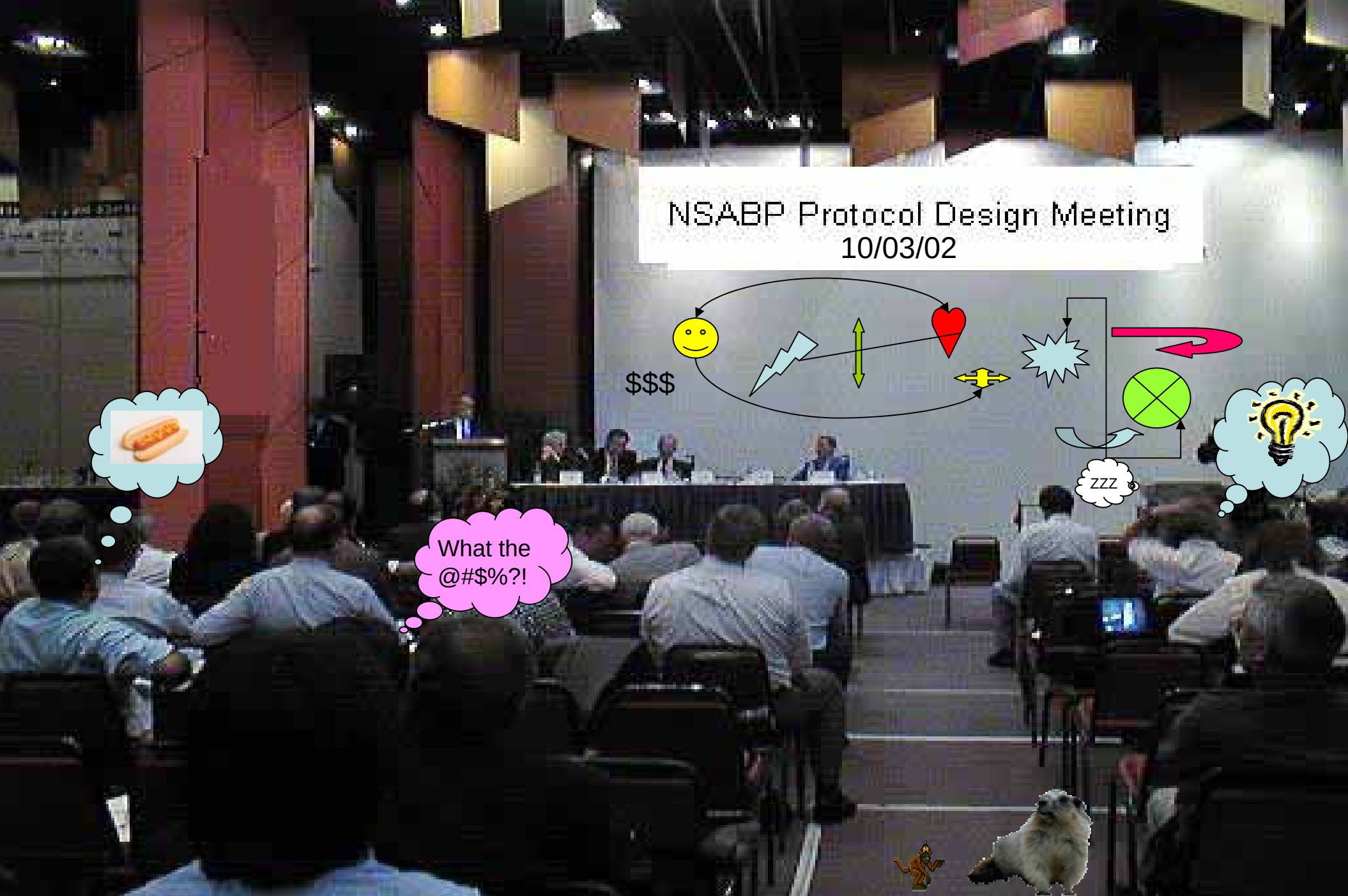



Saint Sebastian


NSABP Protocol Design Meeting
10/03/02
$$$
What the @#$%?!
zzz

NCI APBI MEETING BETHESDA 12/08/02

PHASE III TRIAL
CONCEPT SUBMISSION

CLINICAL INVESTIGATIONS
BRANCH

National Cancer Institute
Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

NOTES: Concepts must be submitted in electronic format, using Word 95 or WordPerfect for Windows 7.0 (tables or schema may be converted to .pdf format to assure accurate transfer). To complete the form electronically, use the mouse pointer or the Tab key to navigate. Select and enter text for each text field. Submit by e-mail to PVG@CTEP.NCI.NIH.GOV or by Windows-formatted floppy disk sent to the address listed on the last page of this document. Each of the scientific sections should be sufficient to constitute the corresponding sections of a final protocol, but they should not be excessive or encyclopedic. Within these principles as a guide, there are no specific requirements or limitations on length.

I. ADMINISTRATIVE

Title of Concept:	A Randomized Phase III Study of Conventional Whole Breast Radiation Therapy (WBT) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer
Sponsoring Organization's Local Protocol Number:	

Study Chair Name (printed):	Frank Vicini, MD
Study Chair Signature (not required):	Date: March 20, 2003
Study Chair Address:	NSABP Operations Center Four Allegheny Center – 5th Floor Pittsburgh, PA 15212-5234
Study Chair Phone:	412-330-4600
Study Chair Fax:	412-330-4661
Study Chair e-mail:	joyce.mull@nsabp.org
Name(s) of co-chair or discipline chairs, if any:	Douglas Arthur, MD, Robert Kuske, MD

Statistical/Data Management Office(s) (Must be NIH Funded. If not currently responsible for large scale NCI clinical trials, submit a separate document describing data management resources to be used for the trial, and Data Safety & Monitoring Board):

Name of Responsible Individual (Printed):	John Bryant, PhD
Signature of Responsible Individual (required):	Date:
Responsible Individual Address:	NSABP Biostatistical Center One Sterling Plaza, 201 North Craig Street, Suite 300 Pittsburgh, PA 15213
Responsible Individual Phone:	412-383-2554
Responsible Individual Fax:	412-383-1387
Responsible Individual E-mail:	bryant@nsabp.pitt.edu
NIH Grant Number:	NSABP Operations Center: U10CA12027 U10CA37377 NSABP Biostatistical Center: U10CA69651 U10CA69974

Anticipated participant(s) – Institutions/Groups expected to accrue patients (include letters committing support). For Genitourinary or Lung protocols, this section is not required:

NSABP Membership
Cancer Trials Support Unit (CTSU)

MARCH 20,2003

NCI-NSABP-RTOG MEETING 9/05/03

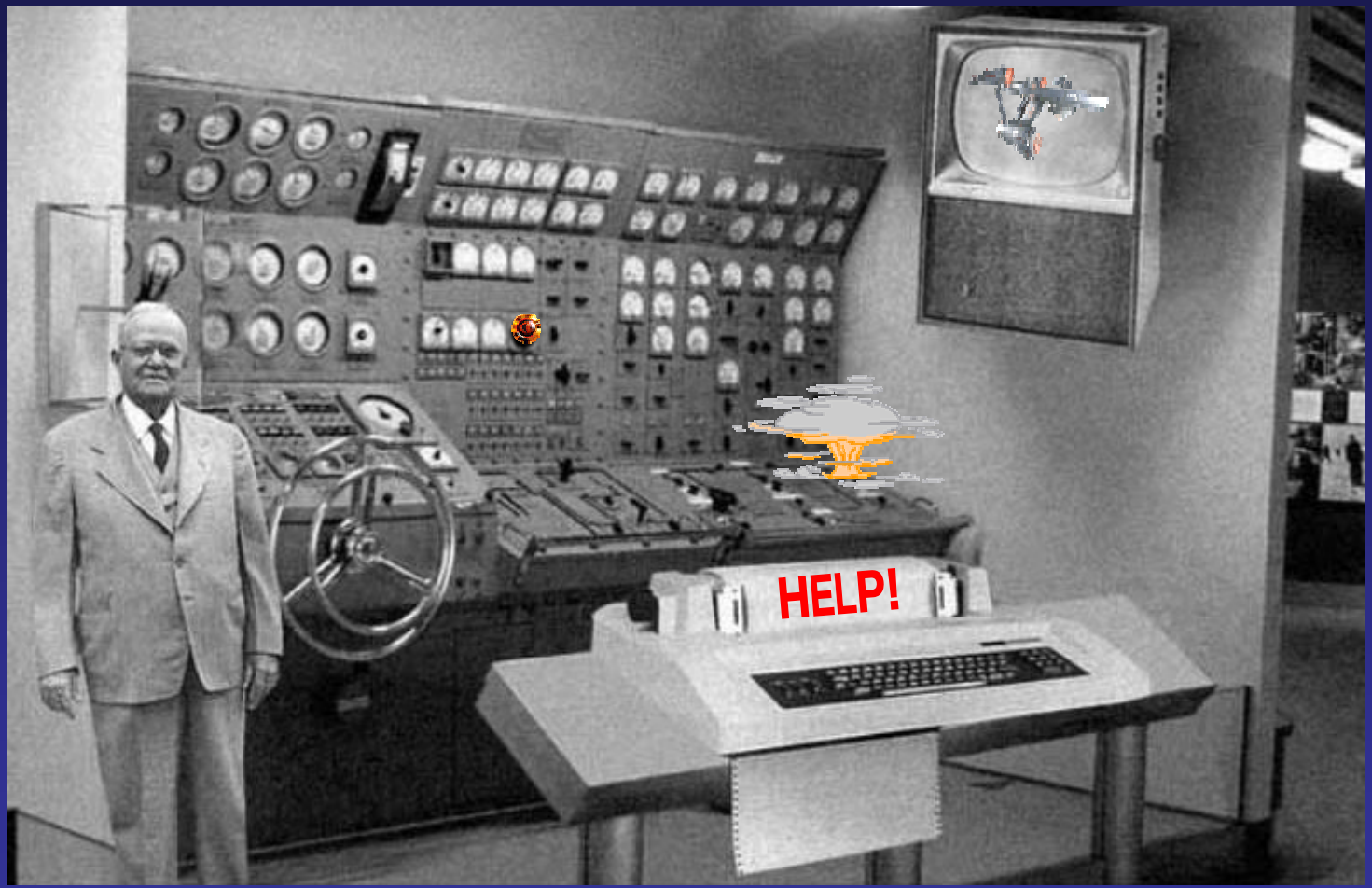
NSABP

NCI

RPC

ITC

RTOG


HELP!

Frank Vicini, M.D.

NSABP Chair

Julia White, M.D

RTOG Chair

Doug Arthur, M.D.

NSABP Co-Chair

Robert Kuske, M.D

NSABP Co-Chair.

Rachel Rabinovitch, M.D.

RTOG Co-Chair

Stephanie Land, Ph.D.

NSABP Statistician

David Parda, M.D.

NSABP Radiation Protocol Officer

Thomas B. Julian, M.D.

NSABP Protocol Officer

Barb Harkins

Deb Davison

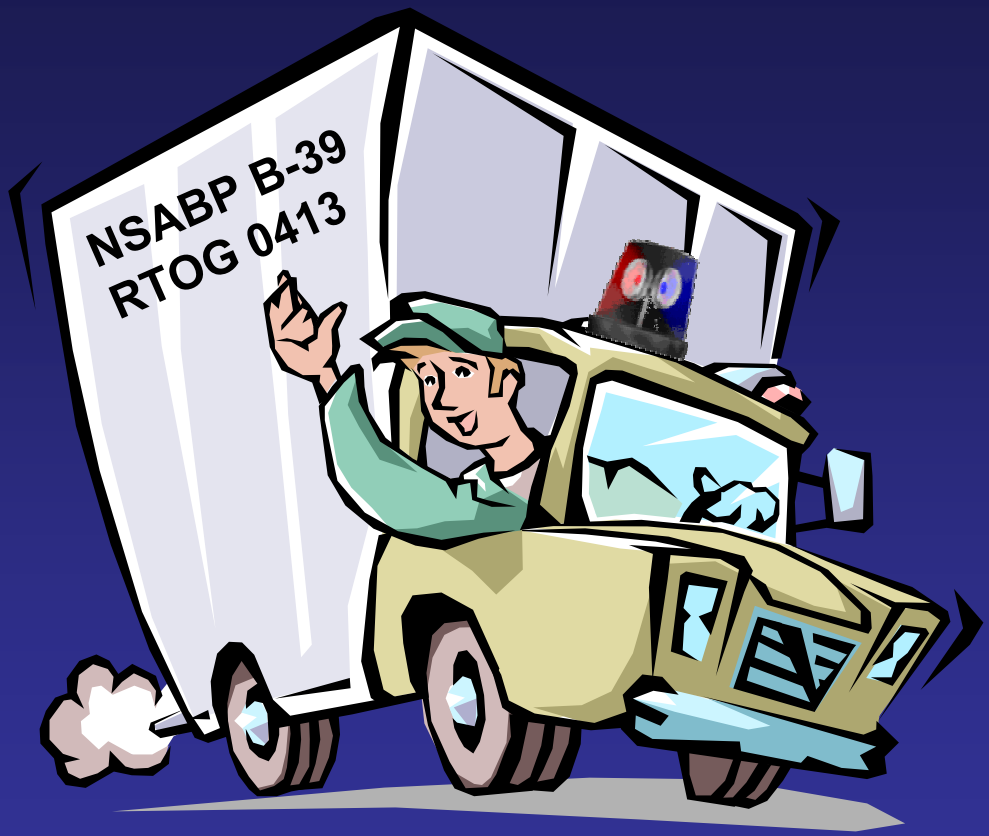
Melissa Nelson

Francy Fonzi

NSABP OPERATIONS

RTOG OPERATIONS

Charlene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RTOG 0413

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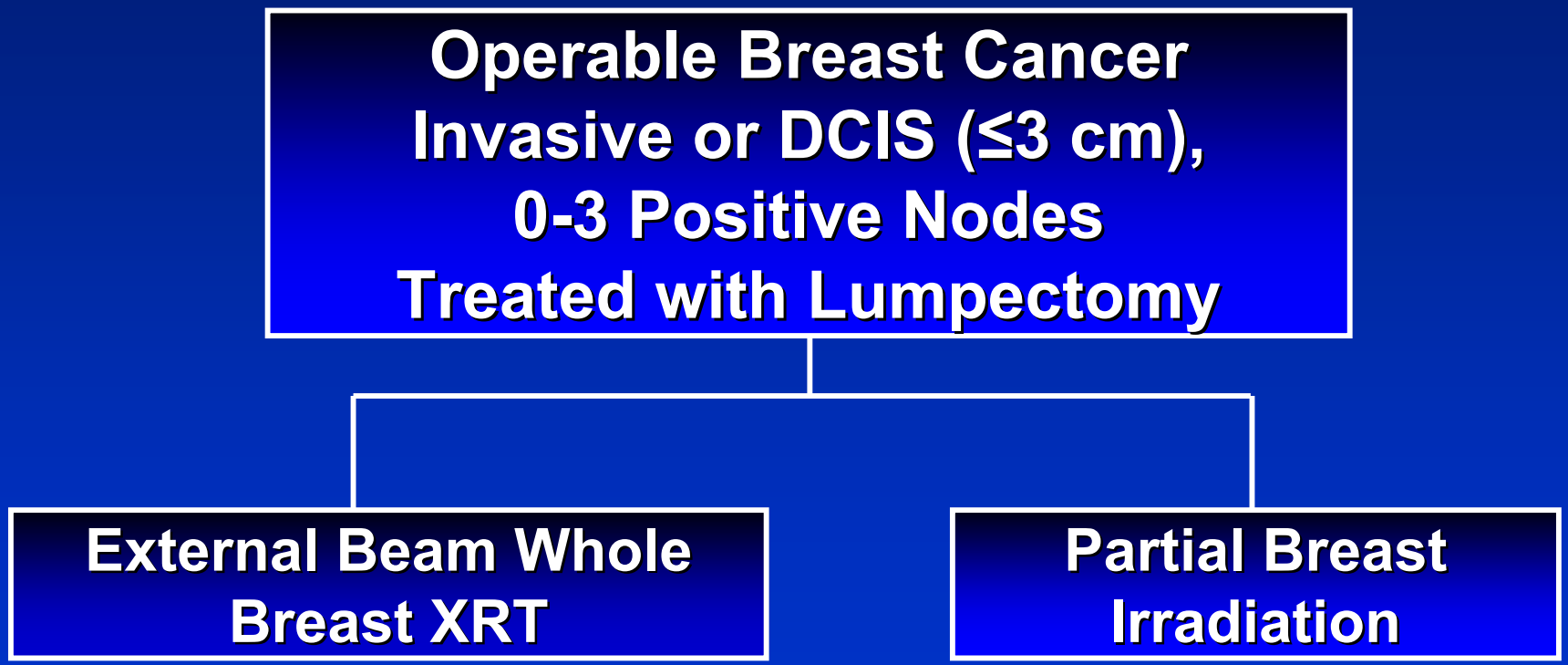
Phase III Trial of Whole Breast Irradiation (WBI)

vs.

Partial Breast Irradiation (PBI)



Athena-
Greek Goddess
Of Wisdom

Accrual Management

- NSABP is the “lead” group (CTSU).
- Any NSABP site (single or multiple groups) can randomize only through NSABP.
- Non-NSABP sites must randomize through CTSU.

Accrual Management

- This Trial involves surgery and radiation therapy.
- The Trial requires long term follow-up
- Site capabilities will vary.
- Dual sites - one group may be more established and better able to conduct the Trial.

Accrual Management

- At sites with active NSABP and RTOG membership, the local NSABP and RTOG PIs have the option (after joint agreement) of electing all accrual from that site to be credited to the RTOG.
- If electing RTOG, entry and randomization would occur through the CTSU. Otherwise, entry and randomization would go through NSABP.
- Renewal of this arrangement could occur on an annual basis, but the recommendation would be to maintain this for the duration of trial accrual.

Accrual Management

- A declaration form will be developed for signature of both the NSABP and the RTOG local PIs and submitted to the NSABP Headquarters.
- CTSU will be notified of the decision rules.
- NSABP sites that elect to award accrual through RTOG will receive full accrual credits toward the 10 patients/year requirement.
- RTOG sites that elect to award accrual through NSABP will receive full accrual credits toward the yearly requirement.

Accrual Management

- Accrual credits will not be retroactive after the joint agreement.
- NSABP will develop an accrual reporting process to RTOG.
- Federal funding for this Trial is approximately $2,000 per randomization from either the NSABP or RTOG. Funding allocation at a site is a local matter. The NSABP and RTOG memberships are strongly encouraged to discuss with each other the allocation issues at their respective sites.

Data Management

- NSABP is the owner of all data and will be responsible for primary/secondary endpoint analyses and QOL analysis.
- RTOG will collect cosmesis data and provide analysis.
- NSABP will manage randomization and with RPC/ITC manage PBI treatment planning data for credentialing and QA/QC.
- RTOG will collect and review WBI planning data.


PBI

NSABP

RTOG

THE PINNACLE PBI TRIAL

Michael-
The Archangel